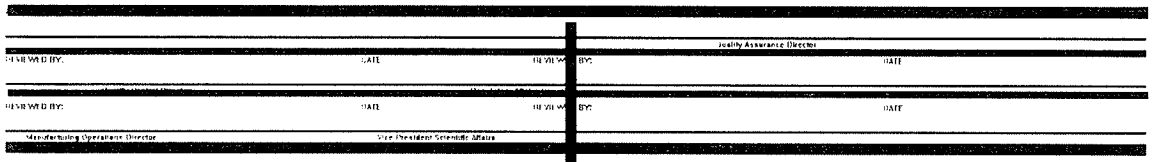
EXHIBIT 128

AMIDE PHARMACEUTICAL, INC.
INVESTIGATION FINAL REPORT

PRODUCT NAME: DIGOXIN TABLETS, 0.25 mg.

CONTROL NO: 3611A **INVESTIGATION NO:** 04-003

DATE INITIATED 7/9/04 **INTERIM REPORT ISSUED** N/A



REASON FOR INVESTIGATION:

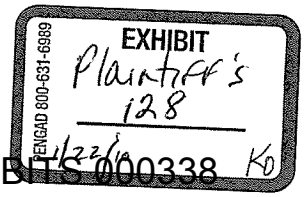
On 7/7/04 Amide received a tablet from a pharmacist at the Rite Aid Pharmacy located at 220 36th Street, Bellingham, WA 98225. The pharmacist indicated that the tablet came from batch 3611A, Digoxin Tablets, 0.25 mg. The tablet has the correct logo, "9/32" standard concave bisect embossed "B 146", as specified for Digoxin Tablets, 0.25 mg.

However, the tablet is thicker than the normal Digoxin tablet. The tablet was measured and found to be 5.71 mm thick as compared to the thickness specification range of 2.7 – 3.7 mm for Digoxin Tablets, 0.25 mg. The tablet was also weighed and was found to weigh 0.272 grams as compared to the weight specification range of 0.114 – 0.126 grams for Digoxin Tablets, 0.25 mg.

LIST OF POSSIBLE CAUSES:

A definitive cause for this very thick tablet was not identified. The most probable cause was that this was a tablet formed during the initial setup of the compression machine. The tablet was not removed from the compression equipment / deduster before starting the production run. However, for purposes of clarity, other possible causes that were evaluated during the investigation are included below:

The thick tablet was formed during the production run
The tablet is actually two tablets stuck together
The tablet was not removed from the tablet collection bucket prior to startup



RESULTS OF INVESTIGATION

The manufacturing batch record for batch 3611A was reviewed. The subject batch was compressed on machines #67 and #71 in rooms #119 and #120 on November 6, 7, and 10, 2003. There was no indication of any weight or thickness problems during the production run. All processing parameters were correctly followed, and all test results were within specification.

Once machine #67 (Stokes BB2) was released for startup, there were 74 weight checks (740 tablets) performed during the production run. The tablet weight per 10 average test result was 1.207 grams versus a specification range of 1.176 - 1.224 grams. The highest weight per 10 test result was 1.220 grams. The average tablet thickness result was 3.16 mm versus a specification range of 2.7 – 3.7 mm. The thickest tablet result was 3.25 mm. Deduster 123 was used in conjunction with this machine.

Once machine #71 (Stokes Pennwolf) was released for startup, there were 78 weight checks (780 tablets) performed during the production run. The tablet weight per 10 average test result was 1.209 grams versus a specification range of 1.176 - 1.224 grams. The highest weight per 10 test result was 1.222 grams. The average tablet thickness result was 3.18 mm versus a specification range of 2.7 – 3.7 mm. The thickest tablet result was 3.24 mm. Deduster 124 was used in conjunction with this machine.

The QA in-process testing results were also reviewed. For machines #67 and #71, the combined QA results showed an average tablet weight of 0.121 grams (740 tablets tested) versus a specification range of 0.114 – 0.126 grams. The average tablet thickness was 3.20 mm (370 tablets tested) versus a specification range of 2.7 – 3.7 mm. Again, all test results were within specification.

The tablet was examined to see if it could possibly be two tablets stuck together. There was no separation at the tablet midpoint and appeared to be a single tablet. This is also supported by the design of the compression machines. Once a tablet is compressed and the machine turntable approaches the tablet discharge location, the bottom punch rides up on a cam and pushes the tablet up above the surface of the turntable. When this occurs, the tablet is freed from the turntable and slides toward the discharge chute. Should a tablet remain stuck to the bottom punch, as the turntable reaches the discharge location the punch slides under a scraper arm where the scraper would force the tablet from the punch. This would cause the tablet to move to the discharge chute. Therefore, there is no possibility of a second tablet being compressed on top of the first tablet.

The possibility of the very thick tablet being formed during the production run was also discussed. For a very thick tablet to be formed during production, the compression machine would have to be setup incorrectly in either of two ways. First, the entire machine would have to be setup in such a way as to allow the compression of overly thick tablets at all 45 stations. A review of the in-process data shows that this did not occur. Or second, the tooling at a single station would have to be incorrectly setup to form overly thick tablets. These thick tablets would be produced throughout the production run, unless

detected by the Production Operators or QA Inspectors. No overly thick tablets were seen throughout the run in either the manufacturing or QA in-process samples. There were no comments in the Batch Record related to any weight or thickness issues. Also, for QA to release the machines for startup, a tablet from every station is sampled and inspected per the Departmental Operating Instructions. If one station had been incorrectly setup to form overly thick tablets, the QA inspection would have seen the defect and would have required a correction before startup release was given. This would prevent any overly thick tablets from being produced during the production run.

The concept that a tablet remained in the compressed tablet collection bucket and was not rejected prior to the line startup could not be dismissed as a possible cause. However, the operators dump the collection buckets into the reject container prior to line startup and it is unlikely that a tablet remained in the bucket. The corrective action implemented addresses both the tablet remaining in the bucket scenario as well as the tablet remaining in the deduster.

CONCLUSION

The most probable cause for the thick tablet was that this was a tablet formed during the initial setup of the compression machine, the tablet became stuck in the deduster, and the tablet was not removed / detected prior to starting the run. The current procedure is that the manufacturing operator requests a QA startup check once the operator has setup the compression machine to produce tablets within the required specifications. When QA confirms that all tablets meet the specifications, the equipment is cleared of any setup tablets and the equipment release is given. As part of this clearance, the deduster (vibrator) is turned on to show that there are no more tablets in the deduster. The vibrator has normally been operated at a slow vibration setting during this step because only a small number of tablets have been produced during setup. It is believed that the tablet in question was stuck in the tablet deduster (vibrator), was not dislodged at the slow vibrator setting, and was not seen by either Manufacturing or QA prior to the equipment being released for production.

CORRECTIVE ACTION

Production and Quality Assurance Departmental Operating Instructions QA-015, PRD-084, and PRD-085 have been revised to include specific steps for verifying and documenting the clearance of the press, deduster, and any associated "acceptable tablet" collection containers. Manufacturing operators will clear the dedusters by operating the deduster vibrators at the maximum vibration setting. This procedural clarification will apply to all compression equipment and all tablet production. Training has been conducted for the Compression Operators, Compression Supervisor, QA Inspectors, and QA Supervisor. See the attached documentation.

DISPOSITION OF INVOLVED BATCHES

No further action is required for Batch 3611A. The batch will remain in distribution.

CHECKLIST SUMMARY

Batch Record Review
See Report.

Cleaning/Usage Log Review
N/A

List of Other Batches
This is an isolated incident and is specific to only Batch 3611A. No other customer complaints have been received pertaining to this issue.

Review of Incoming Raw Material Data
N/A

List of Equipment Involved
See Report.

Verification that Equipment was Functional and Calibrated.
See Report. The scales and test equipment used to evaluate tablets from Batch 3611A were all in calibration. The equipment was found to be functional in that the testing data from Batch 3611A was comparable to previous batches of Digoxin Tablets, 0.25 mg.

Possibility of Equipment Failure
N/A

Maintenance Log Review
N/A

Employee Interviews
The Compression Department Supervisor, the individual who operated the equipment, and two other Compression Operators were all involved in the discussions surrounding this incident. All four individuals identified the tablet in question as a setup tablet when they were first shown the tablet.

Verification of Training
The employees involved are adequately trained.

Need to Include Other Batches
Batch 3611A was the first batch in a 4 batch campaign. The thick tablet issue was not seen in the in-process data for any of the 4 batches and has not been seen in any other Customer Complaints.

Established Procedures Followed
The correct procedures were followed. See report.

List of Possible Causes
See report.

Available Test Result Review
See report for a summary of in-process test results.

Need for Additional Testing
N/A

Need for Revalidation, Requalification, or Additional Stability
N/A

SOP / DOI Review
Department Operating Instructions QA-015, PRD-084, and PRD-085 have been revised to include specific steps for verifying and documenting the clearance of the press, deduster and any associated "acceptable tablet" collection containers prior to machine start up.

Determination of Recurring Problem
No previous incidents of this type have been encountered and this is considered to be an isolated incident.